

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application of: Michael L. Boyer, *et al.*

Confirmation No.: 2300

Application No.: 09/814,214

Art Unit: 3738

Filed: March 22, 2001

Examiner: Chattopadhyay, U.

For: BONE IMPLANTS WITH
CENTRAL CHAMBERS

Attorney Docket No.: 8932-342

BRIEF ON APPEAL FEE TRANSMITTAL

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Commissioner for Patents
PO Box 1450
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Sir:

An original and two copies of the Applicants' Brief on Appeal in the above-entitled application are submitted herewith. The item(s) checked below apply:

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Date: May 27, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application of: Michael L. Boyer II

Confirmation No.: 2300

Application No.: 09/814,214

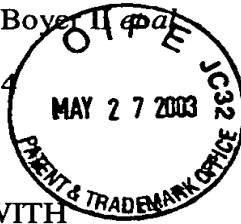
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#17
Brief of
Appeal
J. Boyce
6/3/03

BRIEF ON APPEAL

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

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TECHNOLOGY CENTER R3700

Sir:

Pursuant to the provisions of 37 C.F.R. § 1.191 and § 1.192, this is an appeal from the Examiner's final rejection dated October 23, 2002, rejecting claims 1-6, 8-15, and 24-34 of the above-identified application. Appellant timely filed a Notice of Appeal on February 24, 2003. An original and two copies of this Brief are submitted herewith.

REAL PARTY IN INTEREST - 37 C.F.R. § 192(C)(1)

The real party in interest is Synthes (USA), a general partnership existing under the laws of the Commonwealth of Pennsylvania and having a place of business at 1690 Russell Road, Paoli, Pennsylvania 19301. Synthes (USA) is the assignee of the present application by virtue of an assignment recorded August 2, 2001 at Reel 012034, Frame 0633.

RELATED APPEALS AND INTERFERENCES - 37 C.F.R. § 1.192(C)(2)

There are no related appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

STATUS OF CLAIMS - 37 C.F.R. § 1.192(C)(3)

Claims 1-34 are pending in this application. Claims 1-6, 8-15, and 24-34 stand rejected and are the subject of this appeal.¹ The appealed claims are presented in Appendix A attached hereto.

¹ Although the Examiner has not explicitly indicated that claims 7 and 16-23 stand allowed, none of these claims currently stand rejected.

STATUS OF AMENDMENTS - 37 C.F.R. § 1.192(C)(4)

In response to the final Office Action, an Amendment was filed on February 24, 2003 in which none of the claims were amended. The Examiner stated in an Advisory Action mailed on March 19, 2003 that "Applicant's reply has overcome the following rejection(s): 112, 2nd paragraph of claim 7; 102(e) of claims 7, 16-19, 23; 103(a) of claims 20-22." No amendments currently remain as "unentered" by the Examiner.

SUMMARY OF THE INVENTION - 37 C.F.R. § 1.192(C)(5)

This invention relates to an implant for orthopedic applications, and more particularly, an implant formed from two or more bone portions. (*See, e.g.*, specification at 1:12-13; Fig. 26). Bone grafts have become an important and accepted means for treating bone fractures and defects. (*Id.*, 1:17-18). Bone grafting involves the surgical transplantation of pieces of bone within the body. (*Id.*, 1:22-23). Prior art implants are produced with an inefficient use of source bones. (*Id.*, 5:20-21). Thus, there is a need for an implant that allows more efficient use of source material. (*Id.*, 6:30-31). More specifically, there is a need for an implant that is an integrated implant comprising two or more bone fragments that are interlocked to form a mechanically effective, strong unit. (*Id.*, 6:31-33). In one embodiment, an implant 1550 is fabricated from two pieces of bone 1552, 1554 provided with interlocking ridges 1560 and grooves 1562 and retained together, for example, with pins 1564 passing through aligned holes 1566 in the two pieces 1552, 1554. (*Id.*, 29:5-18; Fig. 26).

ISSUES ON APPEAL - 37 C.F.R. § 1.192(C)(6)

- (1) Whether claims 1-3, 8-13, 24, and 27-31 are anticipated, within the meaning of 35 U.S.C. § 102(e), by U.S. Patent Application Publication No. 2002/0138143 A1 to Grooms *et al.* ("Grooms '143 publication");
- (2) Whether claims 4-6, 14, 15, 32, and 33 are obvious, within the meaning of 35 U.S.C. § 103(a), based on the teachings of the Grooms '143 publication in view of U.S. Patent No. 6,123,731 to Boyce *et al.* ("Boyce '731 patent");
- (3) Whether claims 26 and 34 are obvious, within the meaning of 35 U.S.C. § 103(a), based on the teachings of the Grooms '143 publication in view of U.S. Patent No. 5,989,289 to Coates *et al.* ("Coates '289 patent"); and

(4) Whether claim 25 is obvious, within the meaning of 35 U.S.C. § 103(a), based on the teachings of the Grooms '143 publication in view of U.S. Patent No. 5,895,426 to Scarborough *et al.* ("Scarborough '426 patent").

GROUPING OF CLAIMS - 37 C.F.R. § 1.192(C)(7)

For purposes of this appeal and without prejudice to showing the patentability of the dependent claims, the claims are grouped as follows:

Claims 1-3, 8-13, 24, and 27-31 stand or fall together; and

Claims 4-6, 14, 15, 25, 26, and 32-34 stand or fall together.

ARGUMENT

A. Claims 1-3, 8-13, 24, and 27-31 are not anticipated by the Grooms '143 Publication.

Claims 1-3, 8-13, 24, and 27-31 were rejected under 35 U.S.C. § 102(e) as being anticipated by the Grooms '143 publication. The Office Action stated:

Grooms *et al.* discloses a cortical bone cervical fusion implant with all the elements of claims 1, 16 and 27. See Figure 8A and paragraphs [0010], [0018], [0024] and [0049] for bone fusion implant (800) comprising a hollow body with a completely enclosed hollow region (when fragments are connected) formed between at least two bone fragments (801A, 801B) which are configured and dimensioned for mutual engagement and which are coupled together.

(Office Action, October 23, 2002, Page 3, lines 22-26).

Applicants' invention, as presented in independent claim 1, is directed to a bone fusion implant for repair or replacement of bone comprising a hollow body with a substantially enclosed hollow region formed between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together.

Applicants' invention, as presented in independent claim 27, is directed to a bone fusion implant for repair or replacement of bone comprising: a substantially enclosed hollow interior space formed between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together; and an outer surface conforming in shape with the end plates of vertebrae and having at least one migration resistant feature thereon.

For the reasons that follow, Applicants respectfully submit that the Grooms '143 publication does not anticipate pending independent claims 1 or 27, or claims 2-3, 8-13, 24, and 28-31 that depend therefrom.

1. Grooms does not show each and every element of claims 1 and 27.

To anticipate a claim under 35 U.S.C. §102, a single prior art reference must disclose each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the invention in possession of the public. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985).

The Grooms '143 publication is directed to a cortical bone cervical Smith-Robinson fusion implant. Referring to Fig. 8A of the Grooms '143 publication, reproduced herein, implant 800 is composed of two side-by-side halves, 801A and 801B, that together form a "D"-shaped profile. According to Grooms, the two halves of the implant are brought into juxtaposition to form a unitary implant. (Grooms, Paragraph 49, lines 3-6). A "D"-shaped internal canal may be provided, for example, to permit a purchase (a "key way") within the implant for external machining of the implant. (*Id.*, Paragraph 37, 14-21). As shown in Fig. 4A of Grooms, the spindle 420 of a lathe 400 may be accommodated in the "D"-shaped keyway. (*See, e.g.*, Grooms, Paragraph 42).

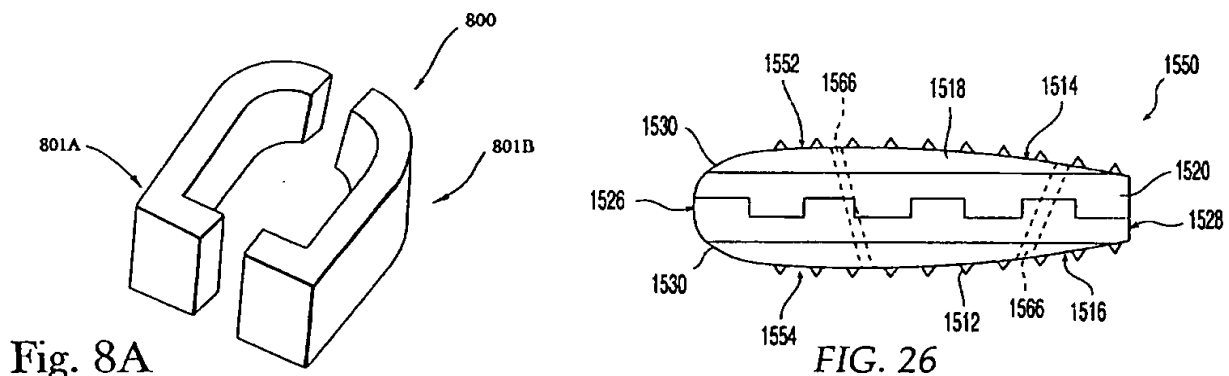


Fig. 8A of the Grooms '143 publication (left) compared to Fig. 26 of the pending application (right).²

In contrast, as shown for example in Fig. 26 of the present application, an implant 1550 comprises a top portion 1552 joined to a bottom portion 1554. (*See, e.g.*, specification at 29:4-5). As it may be difficult to obtain a single section of allogenic bone from which implant 1550 is to be made, fabricating implant 1550 in two pieces, *i.e.*, top and bottom portions 1552, 1554, allows smaller sections of allogenic bone to be used. (*Id.*, 29:5-8). A top connecting surface 1556 and a bottom connecting surface 1558 define the interface between top and bottom portions 1552, 1554. (*Id.*, 29:8-9). Top and bottom surfaces 1556,

² This comparison is not to scale.

1558 have ridges that mate with grooves to interlock top and bottom portions 1552, 1554. (*Id.*, 29:9-11). A pin 1564 passing through aligned holes 1566 in top and bottom portions 1552, 1554 serves to retain top and bottom portions 1552, 1554 together. (*Id.*, 29:15-16). The number and orientation of pins 1564 can be varied. (*Id.*, 29:18). The implant can be provided with a hollow interior to form an interior space. (*See, e.g., Id.*, 28:23-24). This interior space can be filled with bone chips or any other osteoconductive material to further promote the formation of new bone. (*See, e.g., Id.*, 24-26).

} describing
diff. embod.
Fig. 21

The Grooms '143 publication is understood to be silent at least with respect to *a substantially enclosed hollow region*, as recited in Applicants' pending independent claims 1 and 27. "It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation." *In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990) (citations omitted) (emphasis added). Nevertheless, the final rejection appears to have arbitrarily concluded that the "D"-shaped implant shown in Fig. 8A of the Grooms '143 publication allegedly meets the limitations of Applicants' claims. In so doing, the Office Action appears to unreasonably construe the open-ended "D"-shaped key way of Grooms as providing a substantially enclosed hollow region. Moreover, the Advisory Action stated that "Figure 8A of Grooms et al. clearly shows a hollow body with four sides, thereby forming a substantially enclosed hollow region." (Advisory Action, March 19, 2003). Such a conclusory interpretation of Fig. 8A of Grooms with respect to the rejected claims affords undue breadth to the limitation "substantially enclosed hollow region." Concomitantly, such an interpretation fails to appreciate the very nature of the implant construction depicted in that figure – a clearly *open-ended* structure in which nothing is substantially enclosed.

Words such as "substantially" are often used in claims to prevent a potential infringer from avoiding literal infringement simply by making a minor modification. It is beyond dispute that while such a modifier broadens the term that it modifies to some degree, it cannot be allowed to negate the meaning of the words it modifies. *See, e.g., Borg-Warner Corp. v. Paragon Gear Works, Inc.*, 355 F.2d 400, 403-04 (1st Cir. 1965); *Arvin Industries, Inc. v. Berns Air King Corp.*, 525 F.2d 182 (7th Cir. 1975); *see also York Products Inc. v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1572-73 (Fed. Cir. 1996).

The Advisory Action stated that "[u]se of the word 'substantially' to describe the enclosed hollow region in claims 1 and 27 broadens the scope of the claims." (Advisory Action, March 19, 2003). But Applicants submit, however, that the construction of Fig. 8A of the Grooms '143 publication could only fall within the scope of claims 1 and 27 if the word "substantially" was allowed to negate the meaning of "enclosed hollow region."

Accordingly, the Grooms '143 publication fails to meet all of the limitations of Applicants' independent claims 1 and 27.

2. Dependent Claims 2-3, 8-13, 24, and 28-31.

With respect to dependent claims 2-3, 8-13, 24, and 28-31, Applicants respectfully submit that because these claims define more particular aspects of Applicants' invention in addition to the features and elements of the independent claims from which they depend, these claims also are patentably distinct for the same reasons as independent claims 1 and 27.

B. Dependent claims 4-6, 14, 15, 25, 26, and 32-34 are not obvious in view of the pending § 103(a) rejections.

Claims 4-6, 14, 15, 32, and 33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Grooms '143 publication in view of the Boyce '731 patent.

Claims 26 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Grooms '143 publication in view of the Coates '289 patent.

Finally, claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Grooms '143 publication in view of the Scarborough '426 patent.

A prima facie case of obviousness is established by showing that some objective teaching or suggestion in the applied prior art taken as a whole and/or knowledge generally available to one of ordinary skill in the art would have led that person to the claimed invention, including each and every limitation of the claims, without recourse to the teachings in Applicant's disclosure. See *generally In re Oetiker*, 977 F.2d 1443, 1447-48 (Fed. Cir. 1992) (Nies, J., concurring).

As a threshold matter, none of the cited combinations of references, alone or in combination, disclose much less suggest an implant with ***a substantially enclosed hollow region***. Thus, each of the cited combinations of references clearly fails to render obvious the respectively cited claims because each and every limitation of the cited claims is not taught or suggested by these combinations. Applicants respectfully submit that because claims 4-6, 14, 15, 25, 26, and 32-34 define more particular aspects of Applicants' invention in addition to the features and elements of the independent claims from which they depend, these claims also are patentably distinct for the same reasons as independent claims 1 and 27.

CONCLUSION

Applicants respectfully submit that the final rejections of claims 1-6, 8-15, and 24-34 are in error and should be reversed.

A fee for an extension of time is believed to be due for this submission and a petition for extension of time is submitted concurrently herewith. A Brief on Appeal Fee Transmittal sheet also is submitted concurrently herewith. Should any additional fees be required, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Date: May 27, 2003

Respectfully Submitted,

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For: Brian M. Rothery

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Enclosures

APPENDIX A - APPEALED CLAIMS

1. A bone fusion implant for repair or replacement of bone comprising a hollow body with a substantially enclosed hollow region formed between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together.

2. The implant of claim 1, wherein the at least two bone fragments include a first bone fragment with a first coupling portion and a second bone fragment with a second coupling portion, and wherein the first and second bone fragments are joined together by interfitting together the first and second coupling portions.

3. The implant of claim 2, wherein the first coupling portion is a male coupling portion and the second coupling portion is a female coupling portion so that the bone fragments are mated in a male-female relationship.

4. The implant of claim 3, wherein the male coupling portion is a tenon and the female coupling portion is a mortise.

5. The implant of claim 3, wherein the male coupling portion is a tongue and the female coupling portion is a groove.

6. The implant of claim 1, wherein the fragments are configured and dimensioned to form a dovetail joint.

8. The implant of claim 1, further comprising a core formed of at least one of bone material and bone inducing substances, the core being disposed in the hollow body.

9. The implant of claim 8, wherein the core is formed of cancellous bone with a fluid concentrated therein.

10. The implant of claim 9, wherein the cancellous bone is subjected to mechanical pressure to concentrate the fluid.

11. The implant of claim 10, wherein the mechanical pressure is applied by aspiration.

12. The implant of claim 9, wherein the fluid is concentrated by soaking.

13. The implant of claim 1, wherein the hollow body comprises bone tissue selected from the group consisting of autograft, allograft, xenograft bone tissue, and combinations thereof.

14. The implant of claim 13, wherein the bone tissue of at least one of the bone fragments is partially demineralized or demineralized.

15. The implant of claim 1, wherein at least one of the bone fragments is at least partially dehydrated to mate against another bone fragment.

24. The implant of claim 1, further comprising an outer surface with a contour conforming in shape with the end plates of vertebrae.

25. The implant of claim 1, further comprising an outer surface with a wedge-shaped profile.

26. The implant of claim 1, further comprising a region sized to receive a surgical instrument for facilitating implantation of the implant.

27. A bone fusion implant for repair or replacement of bone comprising:
a substantially enclosed hollow interior space formed between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together; and

an outer surface conforming in shape with the end plates of vertebrae and having at least one migration resistant feature thereon.

28. The implant of claim 27, wherein the at least one migration resistant feature comprises teeth.

29. The implant of claim 27, wherein the at least two bone fragments comprise a first bone fragment with a first coupling portion and a second bone fragment with a second coupling portion, and wherein the first and second bone fragments are joined together by interfitting the first and second coupling portions.

30. The implant of claim 27, further comprising at least one of bone material and bone-growth inducing substance disposed in the interior space.

31. The implant of claim 27, further comprising cancellous bone with a fluid concentrated therein, wherein the cancellous bone is disposed in the interior space.

32. The implant of claim 27, wherein the bone tissue of at least one of the bone fragments is partially demineralized or demineralized.

33. The implant of claim 27, wherein at least one of the bone fragments is at least partially dehydrated to mate with another bone fragment.

34. The implant of claim 27, further comprising a region sized to receive a surgical instrument for facilitating implantation of the implant.